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THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US60/618,695*

Certified by

Jon W. Dudas

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Attorney Docket No. 1001-01

1001-01

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

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This is a request for filing a Provisional Application for Patent under 37 CFR 1.53(c)

Inventor(s) and Residence(s) (city and either state or foreign country):

Last Name	First Name	Middle Name	City	State or Country
Crossman	Arthur	W.	Daytona Beach	Florida

Title: **Vascular Catheter Device and Related Method of Making and Using the Same**

11 Sheets of specification.
5 Sheets of drawings.

Applicants claims small entity status as small business concern (37 CFR §§1.27(a)(2)). The Commissioner is hereby authorized to charge the Small Entity Fee of $80 to See enclosed check no. 2142

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If this invention was made by an agency of the United States Government or under a contract with an agency of the United States Government, the government has certain rights in the invention.

YES ☐ NO ☒

Dated: October 14, 2004

Respectfully submitted,

By: _____
Robert J. Decker (Reg. No. 44,056)

Vascular Catheter Device and Related Method of Making and Using the Same

BACKGROUND OF THE INVENTION

Diagnostic vascular catheterization is a classification of invasive procedures in which a catheter and related are passed into a peripheral vein or artery, through the blood vessels, and into the heart or other vasculature. These procedures permit the study of the heart chambers and the arteries supplying the heart or other vasculatures of the body to diagnose illness or disease. Some examples of diagnostic vascular catheterization are, but not limited thereto, are coronary and peripheral vascular (e.g. renal artery, iliofemoral, aortic, cerebrovascular) angiography (or coronary arteriogaphy and angiography)

Therapeutic vascular catheterization (i.e., interventional catheterization) is a classification of invasive procedures in which a catheter and related are passed into a peripheral vein or artery, through the blood vessels, and into the heart or other vasculature. These procedures are intended primarily for the treatment of cardiac illness and disease as well as other vasculature illnesses and diseases. Often the goals of therapeutic vascular catheterization (interventional catheterization) have some similarities to diagnostic catheterization, except the goal is placement of the catheter to treat an underlying condition. Some examples of therapeutic cardiac catheterization are, but not limited thereto, percutaneous transluminal angioplasty (PTA) (alternatively, percutaneous transluminal coronary angioplasty (PTCA)) percutaneous coronary intervention (PCI), and percutaneous transluminal interventions (PTI). Interventional catherization to include all non-balloon angioplasty mechanisms of vascular lumen enlargement.

Some drawbacks that are associated with the various diagnostic and therapeutic vasculature catheterizations are, but not limited thereto, the unnecessary complications that can occur and restricted operations related to advancing or moving the catheter shaft and catheter tip. For example, the edge of the catheter tip puts pressure on the shoulder of the plaque thus rupturing or injuring the plaque shoulder. As a result this can, for example, release contents of plaque and lead to thrombosis or allow contrast to track between layers of artery (or vein) causing a dissection. Further, if a wire is passed through a catheter then dissection can also occur if the catheter is pushed further forward whereby a layer of the vasculature can be further

separated leading to thrombosis and dissection. Alternatively, while traversing any vascular structure atherosclerotic debris can be dislodged thus leading to embolization of debris and distal vessel occlusion. Accordingly, the amount of force and leverage applied to a catheter is compromised because of the aforementioned and other risks and complications.

There is therefore a need in the art for a more effective and safer method of practicing diagnostic and therapeutic vasculature catheterizations.

BRIEF SUMMARY OF INVENTION

Conventional diagnostic and therapeutic arterial vascular catheters have leading edges that are circular with a non blunt edge similar in shape to a drinking straw, for example. This may lead to vascular trauma due the relatively sharp edge of the catheter disrupting the layers of the vessel or plaque shoulder secondary to pressure exerted and or inherent angulation of the edge interface with the vessel wall.

The various embodiments of the present invention are to provide a blunt, atraumatic distal tip and orifice edge to the catheter. This will eliminate or mitigate catastrophic complications caused by contemporary catheters such as vascular dissection, thrombosis, distal embolization and vessel occlusion. The various embodiments of the present invention catheter tip can be shaped in various ways with solid material (compressible or non-compressible) or balloon inflation devices to create a blunt, atraumatic tip and orifice. The shape can take on numerous forms including, but not limited to olive, bulbous, rounded, spherical, hemispherical, conical, oval, tapered, beveled, chamfered, graduated and/or multi-faceted like a cut diamond (as well as dodecahedron, semi-dodecahedron, icosahedron, or semi- icosahedron, etc.). This would enable atraumatic intubation of all vascular structures. Some advantages associated with some of the embodiments include, but not limited thereto, elimination or mitigation of risks of the aforementioned complications as compared to conventional catheters and provide more aggressive intubation of vascular structures for improved leverage for delivery of therapeutic interventional hardware (i.e. balloons, stents, atherectomy devices, lasers, thrombectomy devices, etc.) in situations where conventional catheters may traumatize the vessel or fail to deliver the therapeutic hardware; secondary to concern for risk of vascular trauma and the

aforementioned complications.

BRIEF SUMMARY OF THE DRAWINGS

The foregoing and other objects, features and advantages of the present invention, as well as the invention itself, will be more fully understood from the following description of preferred embodiments, when read together with the accompanying drawings, in which:

FIG. 1(A) illustrates a schematic elevation view of an embodiment of the present invention catheter device including a distal tip.

FIGS. 1(B)-1(D) illustrate schematic partial views of the catheter device of **FIG. 1(A)** with alternative embodiments of the distal tip.

FIG. 2 illustrates a schematic elevation and partial view of an embodiment of the present invention catheter device including a distal tip.

FIG. 3 illustrates a schematic elevation and partial view of an embodiment of the present invention catheter device including a distal tip.

FIGS. 4(A)-(B) illustrate schematic elevation and partial views of an embodiment of the present invention catheter device including a distal tip having a balloon in a non-inflated state and an inflated state, respectfully.

FIGS. 5(A)-(B) illustrate schematic elevation and partial views of an embodiment of the present invention catheter device including a distal tip having a catheter tip in a non-compressed state and compressed state, respectfully.

FIG. 6(A) is a schematic elevation view of a sheath that has been inserted into a vasculature structure such as an artery, vein, or the like.

FIG. 6(B) is the sheath as shown in **FIG. 6(A)** with the catheter device of **FIGS. 5(A)-(B)** extending there through.

FIGS. 7(A)-(B) illustrate schematic elevation and partial views of an embodiment of the present invention multi-lumen, multi-balloon tipped diagnostic and therapeutic vascular catheter in the non-inflated and inflated state, respectfully.

FIGS. 8(A)-(B) illustrate schematic elevation and partial views of an embodiment of the present invention multi-balloon orifice ring / rim diagnostic and therapeutic vascular catheter in

the non-inflated and inflated state, respectfully. **FIG. 8(C)** illustrates a schematic end view of **FIG. 8(B)**. **FIG. 8(D)** illustrates a schematic partial side view of **FIG. 8(B)**.

DETAILED DESCRIPTION OF THE INVENTION

Some of the embodiments of the present invention provide a diagnostic vascular catheter for imaging or a therapeutic vascular catheter for vascular lumen enlargement that is atraumatic by providing, among other things, the tip of the catheter blunt in shape. It should be appreciated that the embodiments of the present invention distal tip can be utilized with the existing arterial vascular imaging and therapeutic catheters in terms of their proximal portion of the catheter and shaft shape of the catheter with regards to design, and materials. It should be appreciated that some of the embodiments of the present invention distal tip and balloons can utilize materials available in the field.

In an embodiment of the present invention catheter, the distal tip and tip orifice includes, but not limited thereto, the following: 1) solid non-compressible blunt tip and orifice/orifice edge. The material of the non-compressible tip can be composed of some material currently available for catheter tips and orifice leading edges. The leading orifice edge may be rounded toward the catheter lumen creating a smooth, non-edged orifice interface with the leading contacted portion(s) of the endovascular luminal wall tissue. The outer portion of the orifice may also be smooth and blunt in shape and gently flared toward the more proximal portion of the distal tip. This will create a smooth, blunt and atraumatic interface with the non-leading more proximal portion(s) of the contacted endovascular wall tissue. In short, the catheter orifice and distal tip will be shaped much like an olive, blunt tipped cone, sphere, hemisphere, etc. The x, y and z planes as well as the angle of curvature of the proximal and distal flared surfaces of the distal tip can be manipulated along the entire geometric spectrum of potential shapes to create a relatively spherical, olive shaped or conical shaped structure. The angle of curvature of the proximal and distal flared surfaces can also be manipulated along the entire geometric spectrum of curvature to create a relatively more blunt, conical, faceted or angulated structure. The luminal geometry of the catheter tip may remain unchanged in order to accommodate existing contemporary vascular luminal enlarging devices and/or contrast, drugs, fluid, etc. For example,

4 french would remain 4 french, 5 french would remain 5 french etc. Because a flared tip may be a larger French size than the remainder of the catheter shaft, a larger vascular sheath would be required. Up sizing the vascular sheath may be avoided by the following adjustments to the catheter tip and orifice while at the same time maintaining the same geometry as described above. First, the flared distal tip is compressible so for instance if the flared tip is 7 french it can be compressed through a 6 french sheath and reform its atraumatic blunt geometry after traversing the vascular sheath (See for example, **Figs. 5-6**). Second, the distal tip and orifice edge are shaped by an inflatable balloon(s) which may be commence in a deflated state and can be inflated after traversing the vascular sheath and deflated upon removal of the catheter through the vascular sheath(See for example, **Figs. 4-6**) . The balloon is inflated by a separate lumen connected to an inert gas, radiographic contrast, fluid or air delivery system at the operator end of the catheter, for example. Separate lumens, balloons and inflation devices would be required for separate manipulation of x, y and z planes with a larger covering balloon or balloon like material or membrane covering the three x, y and z plane balloons. This would enable more detailed and/or variable shape changes as further elaborated later in the text. Alternatively the "covering" balloon could be optional and/or alternatively the balloon could have a pre-formed shape with only size of the balloon being able to be controlled by the operator. Size of the balloons could be a function of balloon material compliance and inflation pressure as in contemporary ptca balloon material for example. As previously mentioned the geometry of the balloon catheter tip and orifice can take on all shapes along the entire continual geometric spectrum of manipulation of x, y and z planes of the catheter distal tip and orifice to create a relatively conical, olive, ellipsoid, hemispherical, multifaceted or spherical shape with changing of the long and short axes as well as the angle of curvature of the proximal and distal flared surfaces. Size of the balloon tip could also be manipulated by varying the compliance of the balloon material and inflation pressure. Alternatively, the orifice edge itself can exclusively be shaped by solid means (compressible or non-compressible) or balloon inflational means as an atraumatic blunt ring. The ring would be somewhat analogous to an innertube covering the metal edge of a wheel, for example. A difference being that in this case the ring would cover the leading edge of the distal tip orifice. Whether solid or inflatable, compressible or non-compressible the geometry of the ring could be manipulated changing the axes in x, y and z

planes (as detailed above) of the ring inner diameters and lengths respectively to create the entire geometric spectrum of shapes capable with these manipulations. Again this would require separate lumina, with separate inflation devices corresponding to separate balloons in x, y and z planes for the desired effect of shape manipulation. These separate balloons could be covered by a covering balloon material (e.g., outer membrane) or alternatively left bare or alternatively inflated to a pre-formed shape with only size manipulatable. Further advantages of balloon inflation devices would be operator control of x, y and z planes of the balloons thus enabling manipulation of shape as well as size in all planes to optimally and as atraumatically as possible intubate variably shaped and sized vasculature space. In some embodiments, the method of use of this invention may be similar to contemporary diagnostic and therapeutic catheters in some aspects, but with several important safety, design features and options, and therapeutic advantages associated with the present invention. For example, regarding various embodiments of the present invention, from a safety standpoint the blunt, atraumatic edge will allow traversal of all arterial vascular space much less traumatically. The blunt geometry of the present invention catheter and orifice and related will enable contact with the vascular endoluminal wall that is atraumatic. Whereas with regards to some of the drawbacks of conventional catheters, the edge of conventional catheter orifice tips may create dissection planes, lift plaque shoulders, embolize atherosclerotic debris or perforate the vessel with forward motion in arterial vascular lumens. This is due to, for example but not limited thereto, the geometry of the edge which is relatively sharp and thus capable of "digging" into the arterial vascular luminal wall with forward pressure. For example, various angulations and points of pressure will create relatively more pressure on a smaller surface area much like razor blade as opposed dichotomously to a flat surface.

However, turning to various embodiments of the present invention, a flatter more bulbous catheter orifice/tip would be much less traumatic to the arterial luminal surface. Additionally, another advantage associated with embodiments of the present invention is the capability of providing more aggressive delivery of therapeutic vascular devices for vascular luminal enlargement. For instance recent data has suggested that so called direct delivery of stents without balloon predilitation will have multiple advantages. These include less use of radiographic contrast, shorter procedure times and omission of pre-dilatation balloon injury

outside of the stented arterial segment.

Direct stenting is often limited by inability to deliver the undeployed stent secondary to the frequent occurrence of the guiding catheter backing out of the vascular ostia secondary to translation of force backward from obstructing calcium, plaque and/or vascular angulation preventing forward translation of pressure. This problem of device delivery is commonly overcome by using guiding catheters with secondary and tertiary bends enabling leverage from an opposing vascular wall and so called "deep seating" the guiding catheter and/or simply using larger French guiding catheters with similar manipulations. This commonly leads to successful delivery of the device at the expense of risking vascular trauma and the associated catastrophic sequelae such as dissection leading to vessel occlusion, plaque disruption leading to thrombosis and vessel occlusion and vessel perforation all of which have a high risk of leading to death, tissue infarction, stroke, hemorrhage and circulatory collapse as well as emergency surgery.

In contrast, another advantage associated with embodiments of the present invention is the capability of providing deflecting contrast streaming or guide wires away from the vascular luminal wall, thus further diminishing potential vascular trauma. As previously mentioned operator controlled balloon inflation devices of some embodiments of the present invention would allow manipulation of balloon tipped x, y and z planes thus enabling refined control of direction of the catheter tip/orifice and therefore direction of contrast streaming or guide wire direction. Therefore, for instance if the catheter orifice was angulated toward an ulcerated complex plaque, balloon inflation could be performed thus pushing the orifice away from the plaque. The blunt surface of the balloon tip would be relatively atraumatic to the plaque and contrast and/or guide wires would be much less likely to traumatize, dissect, perforate, etc. the vessel. With regards to various embodiments of the present invention, it is feasible that traversal of all vascular space would not even require a J tipped guide wire as the various embodiments of blunt catheter tip would effectively accomplish the same goal. This would decrease procedure cost, eliminate another step in the standard procedure sequence and thus decrease the time of the procedure. Given the extraordinary number of diagnostic and therapeutic vascular procedures performed throughout the world today a substantial amount of morbidity and mortality could be eliminated and/or diminished with this invention.

Furthermore many previously unsuccessful conventional procedures could be rendered

successful due to the ability of the present invention to be more aggressive in device delivery while at the same time reducing risks of vascular trauma and its catastrophic consequences.

Turning to **FIG. 1(A)**, **FIG. 1(A)** illustrates a schematic elevation view of an embodiment of the present invention catheter device **11** including a catheter shaft **12**, interface member **20**, proximal catheter portion **13**, distal catheter portion **15**, and a distal tip **17** having an orifice **19** defined by the lumen of the catheter therein and with an orifice edge **14**. The distal tip **17** is a non-traumatic (i.e., atraumatic) shape such as, but not limited thereto, any of the following: elliptical, spherical, oval, rounded, olive, bulbous, blunt, and rounded. It should be appreciated that the distal tip **17** may not necessarily be entirely elliptical or olive shaped. For example, as shown in **FIG. 1(B)**, the shape of the distal tip **17** may be semi-elliptical, semi-spherical, hemispherical, semi-oval, partly rounded or partly olive. The distal tip **17** provides a blunt and non-traumatic effect or interaction when the catheter shaft **12** or portion thereof and/or distal tip **17** are advanced, translated, turned or moved through the vasculature. It should be appreciated that the interface member **20** may include a number of systems and devices including, but not limited thereto, manifold, flusher, pressure manometer, etc.

Alternatively, as shown in **FIG. 1(C)**, the shape of the distal tip **17** may be tapered, beveled, chamfered, graduated, or multifaceted (e.g., like a diamond or the like (e.g., dodecahedron, semi-dodecahedron, icosahedron, or semi- icosahedron, etc.)). The distal tip **17** shall be tapered, beveled, chamfered, graduated or multifaceted in a manner to provide a blunt and non-traumatic effect or interaction when the catheter shaft **12** or portion thereof and/or distal tip **17** are advanced, translated, turned or moved through the vasculature.

As shown in **FIG. 1(D)**, the shape of the distal tip **17** may conical shaped or substantially conical shaped or the like.

The distal tip **17** may be comprised of a variety of materials including at least one of the following or combinations thereof: elastomeric, rubber, rubber-like, plastic, and polymer. The catheter shaft and related may be comprised of the following materials, as well as other materials available for catheters.

Turning to **FIG. 2**, **FIG. 2** is a schematic elevation view of a partial catheter device **11** including a catheter shaft **12**, proximal catheter portion **13**, distal catheter portion **15** and a distal tip **17** having an orifice **19** defined by the lumen of the catheter therein and with an orifice edge

14. Additionally, a non-inflatable non-traumatic (i.e., atraumatic) ring or rim **18** is provided so as to, among other things, avoid or mitigate complications such as trauma, dissection and interference with the vascular walls or anatomy. This rim may be a variety shapes such as a bumper, balloon or tube, for example. The rim **18** may run continuously around the circumference of the orifice **19** as illustrated, or alternatively, the ring or rim **18** may be semi-continuous, i.e., with individual breaks, segments or interruptions (not shown). As mentioned above, the distal tip **17** may be any one of the following such as, but not limited thereto, any of the following: elliptical, spherical, oval, rounded, olive, bulbous, and rounded. It should be appreciated that the distal tip **17** may not necessarily be entirely elliptical or olive shaped. For example, as shown in **FIG. 1(A)**, the shape of the distal tip **17** may be semi-elliptical, semi-spherical, hemispherical, semi-oval, partly rounded or partly olive. Alternatively, the non-inflatable distal tip **16** may be tapered, beveled, chamfered, graduated, or multifaceted (e.g., like a diamond or the like).

Turning to **FIG. 3**, **FIG. 3** is a schematic elevation view of a partial catheter device **11** including a catheter shaft **12**, proximal catheter portion **13**, distal catheter portion **15** and a distal tip **17** having an orifice **19** defined by the lumen of the catheter therein and with an orifice edge. Additionally, a non-inflatable non-traumatic (i.e., atraumatic) rim **16** is provided so as to avoid or mitigate complications such as trauma, dissection and interference with the vascular walls or anatomy. This non-inflatable ring or rim **16** may be a variety shapes such as a bumper, cushion, or tube, for example. The non-inflatable rim **16** may run continuously around the circumference or perimeter of the orifice **19** as illustrated, or alternatively, the non-inflatable rim **16** may be semi-continuous, i.e., having breaks, segments or interruptions (not shown). As mentioned above, the distal tip **17** may be any one of the following such as, but not limited thereto, any of the following: elliptical, spherical, oval, rounded, olive, bulbous, and rounded. It should be appreciated that the distal tip **16** may not necessarily be entirely elliptical or olive shaped. For example, as shown in **FIG. 1(A)**, the shape of the distal tip **16** may be semi-elliptical, semi-spherical, semi-oval, partly rounded, or partly olive. Alternatively, the distal tip **16** may be tapered, beveled, chamfered, graduated, or multifaceted (e.g., like a diamond or the like(e.g., dodecahedron, semi-dodecahedron, icosahedron, or semi- icosahedron, etc.)).

Turning to **FIG. 4(A)**, **FIG. 4(A)** is a schematic elevation view of a partial catheter

device **111** including a catheter shaft **112**, proximal catheter portion **113**, distal catheter portion **115** and a distal tip **117** having a balloon **131** (shown in a non-inflated state) or any inflatable means located proximally to or immediately at the orifice **119**. Turning to **FIG. 4(B)**, **FIG. 4(B)** illustrates the partial catheter device **111** of **FIG. 4(A)** with the balloon **131** (or any inflatable means) in an inflated state. The inflated balloon **131** (or any inflatable device) provides a blunt effect or interaction when the catheter shaft **112** or portion thereof and/or distal tip **117** are advanced, translated, turned or moved through the vasculature.

Turning to **FIG. 5(A)**, **FIG. 5(A)** is a schematic elevation view of a partial catheter device **211**, including a catheter shaft **212**, proximal catheter portion **213**, distal catheter portion **215** and a distal tip **217** having an orifice **219** wherein the tip **217** may have a design as discussed with the embodiments associated with anyone of **FIGS. 1-4.** In addition, the distal tip **217** (as shown in a non-compressed state) is made of a material that is compressible so as to be able to reduce the cross-section as desired or required. Turning to **FIG. 5(B)**, **FIG. 5(B)** illustrates the partial catheter device **211** of **FIG. 5(A)** with the distal tip **217** in the compressed state.

Turning to **FIG. 6(A)**, **FIG. 6(A)** is a schematic elevation view of a sheath **241** that has been inserted into a vasculature structure **243** such as an artery, vein, or the like. **FIG. 6(B)** is the sheath **241** as shown in **FIG. 6(A)** with the catheter device **211** extending there through. The compressible distal tip **217** has cross-section larger than the cross-section of the sheath **241** or lumen **242** of the sheath **241.** During use of the compressible catheter device **211** the catheter **211** is passed through the lumen **242** of the sheath **241** in a compressed state and expands after it exits the end of the sheath **241**. It should be appreciated that the design of the catheter and tip may be as discussed with the embodiments associated with anyone of **FIGS. 1-4**; however the cross-section of the sheath could need to be larger to accommodate a distal tip of a catheter that is not compressible enough to fit through a narrower sheath lumen

In at least some of the embodiments of the present invention, during operation the distal tip of the catheter and/or other aspects of the catheter, the present invention is able to put less pressure on the shoulder of the plaque and/or vasculature walls/structures and therefore avoid or minimize the rupturing, traumatizing or injuring the plaque shoulder and/or vascular walls/structures. As a result, for example, this prevents or minimizes the release of plaque

content which can lead to thrombosis or other illnesses or complications. Similarly, some embodiments of the present invention avoid or mitigate contrast from tracking between layers of artery (or vein) that causes dissection or other injuries. Accordingly, the amount of force and leverage that can be applied to a catheter and catheter tip is improved because the present invention avoids or mitigates any of the aforementioned complications, injuries or illnesses, as well as other existing complications, injuries or illnesses in the field of catheterization.

Additionally, in at least some of the embodiments of the present invention, during operation wherein a wire or other device is passed through the catheter, the present invention avoids or mitigates the occurrence of a dissection. Accordingly, the amount of force and leverage that can be applied to a catheter and catheter tip is improved because the present invention avoids or mitigates any of the aforementioned complications, injuries or illnesses, as well as other existing complications, injuries or illnesses in the field of catheterization.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The foregoing embodiments are therefore to be considered in all respects illustrative rather than limiting of the invention described herein.

1001-01

FIG. 1D

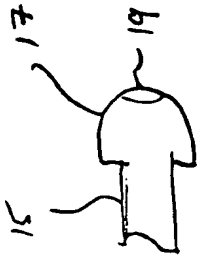

FIG. 1B

FIG. 1C

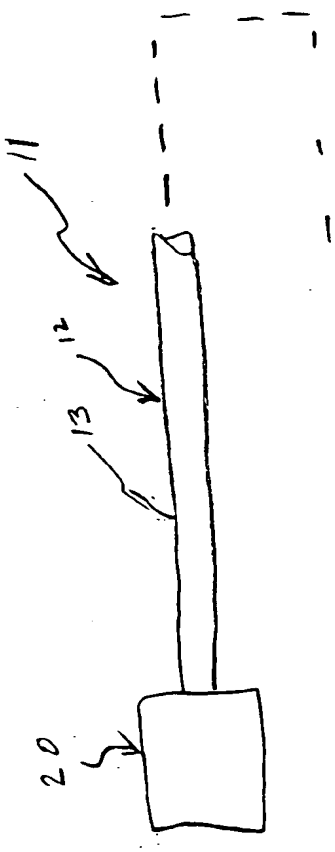

FIG. 1A

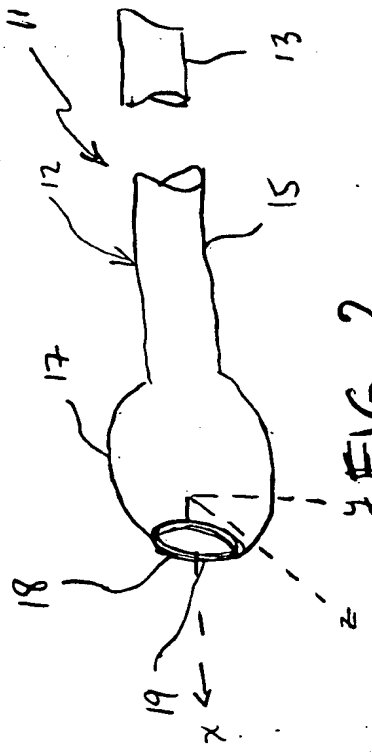

FIG. 2

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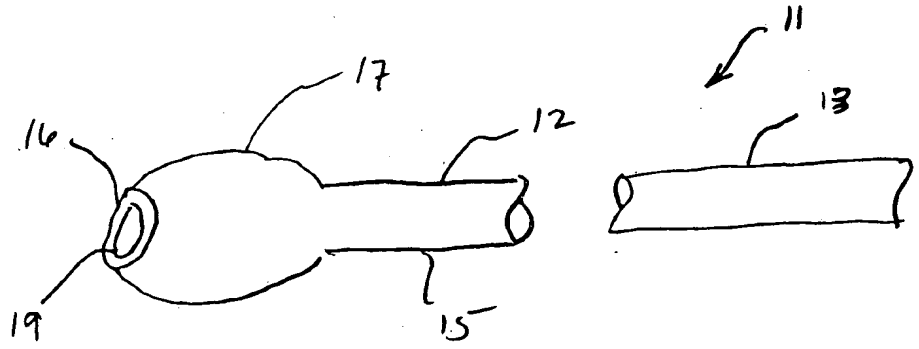


FIG. 3

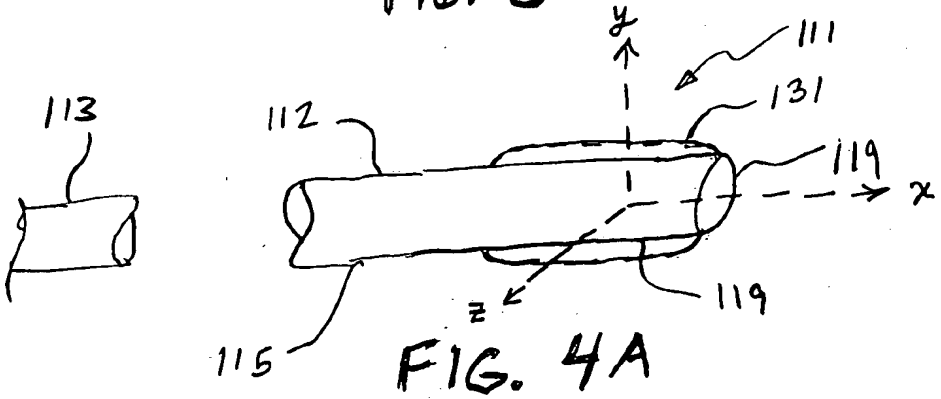


FIG. 4A

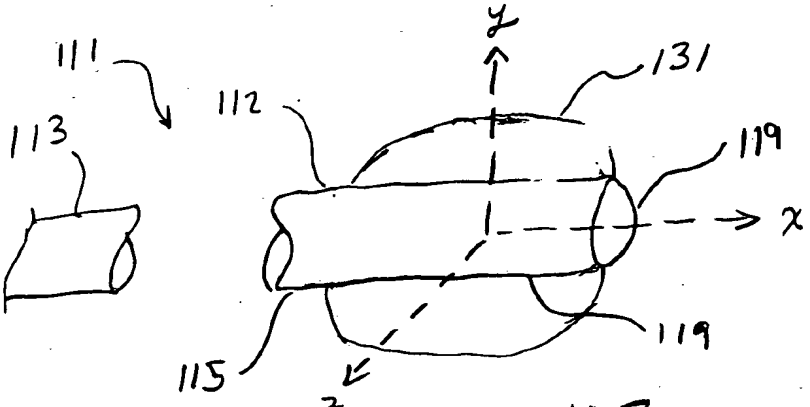


FIG. 4B

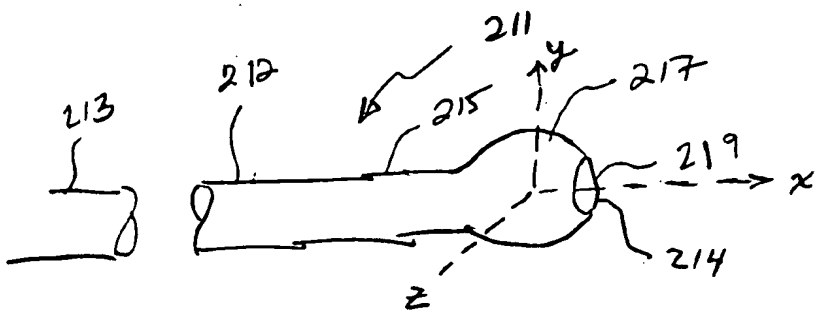


FIG. 5A

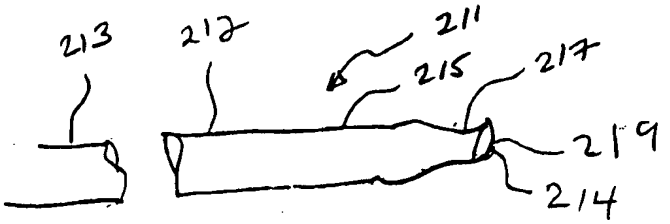


FIG. 5B

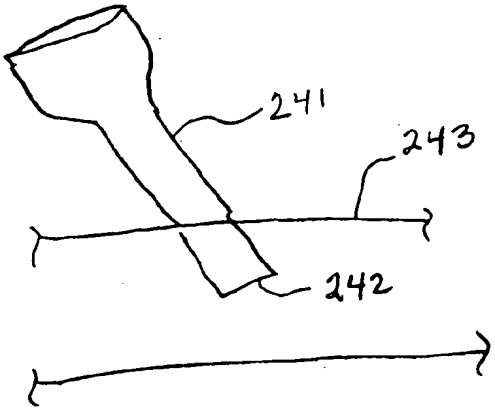


FIG. 6A

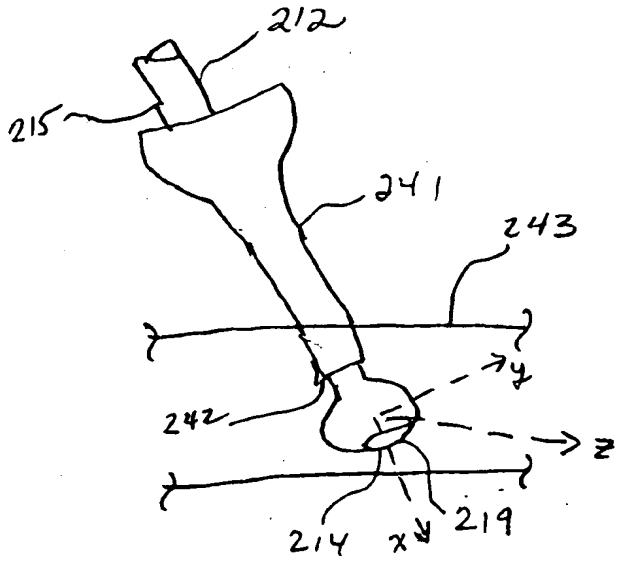


FIG. 6B

1001-01

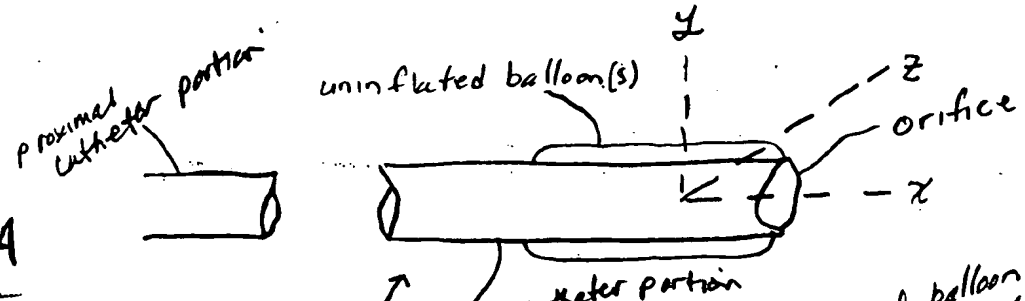


FIG 7A

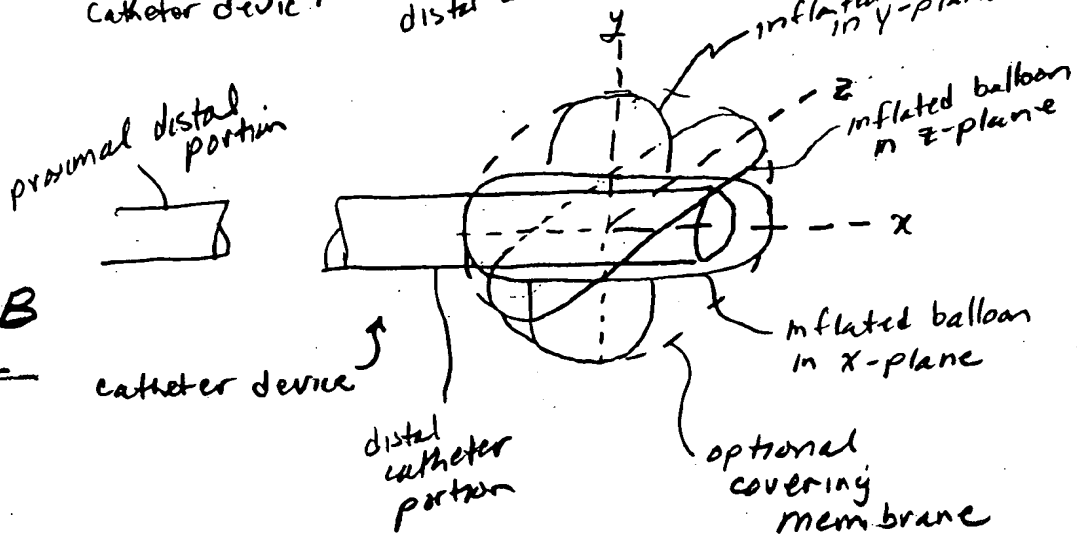


FIG. 7B

Relative inflation in X, Y, Z planes enables variable shape change across the full geometric spectrum of potential shapes

1001-01

FIG. 8D

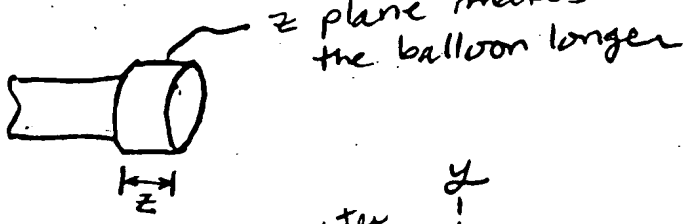


FIG. 8A

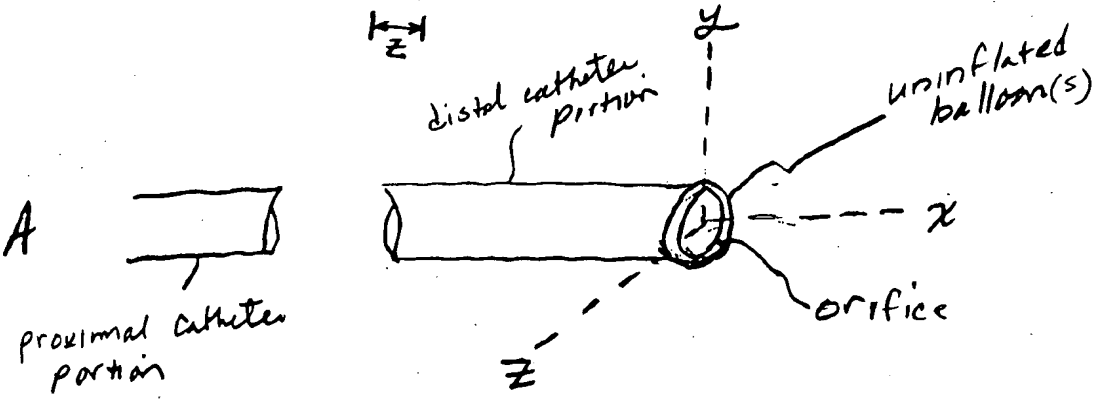


FIG. 8B

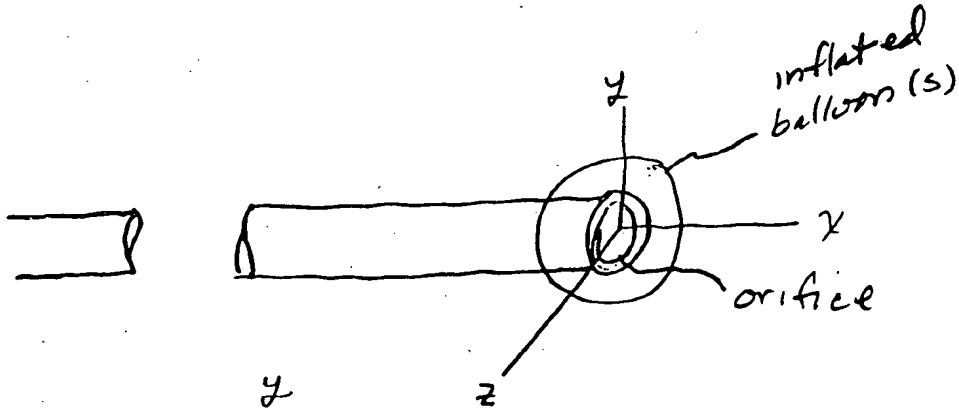
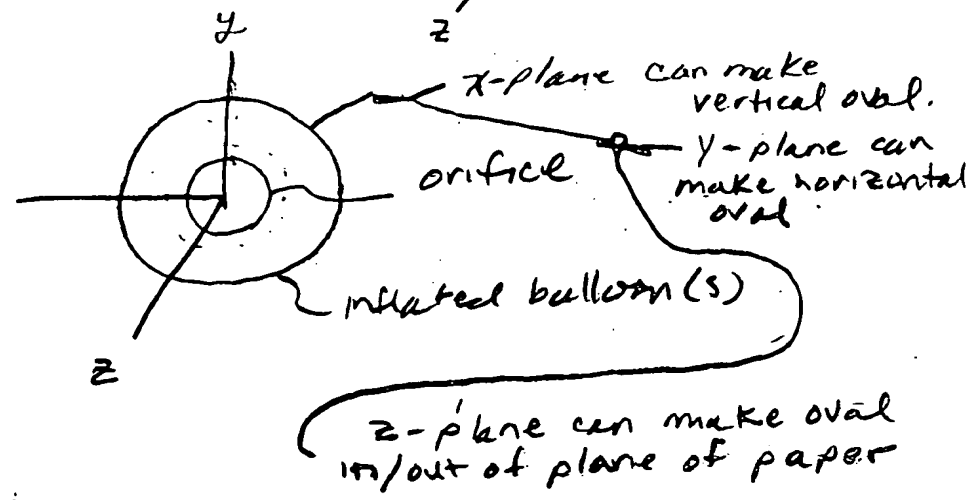


FIG. 8C
(Schematic end view)



From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

DECKER, Robert, J.
2679 Teakwood Drive
Charlottesville, VA 22911
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)* 12 January 2006 (12.01.2006)	
Applicant's or agent's file reference 1001-02	**IMPORTANT NOTIFICATION**
International application No. PCT/US2005/037031	International filing date *(day/month/year)* 14 October 2005 (14.10.2005)
International publication date *(day/month/year)*	Priority date *(day/month/year)* 14 October 2004 (14.10.2004)
Applicant CROSSMAN, Arthur, W.	

1. By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. *(If applicable)* The **letters "NR"** appearing in the right-hand column denote **a priority document which, on the date of mailing of this Form, had not yet been received by the International Bureau** under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

3. *(If applicable)* **An asterisk (*)** appearing next to a date of receipt, in the right-hand column, denotes **a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b)** (the priority document was received after the time limit prescribed in Rule 17.1(a) or the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b)). Even though the priority document was not furnished in compliance with Rule 17.1(a) or (b), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as the priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
14 October 2004 (14.10.2004)	60/618,695	US	16 December 2005 (16.12.2005)

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